National Cancer Institute

caBIG™ cancer Biomedical Informatics Grid ™

Reporting/Sharing Special Interest Group Meeting

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NCI Center for Biomedical Informatics and Information Technology

caBIG™ Clinical Trials Management Systems Workspace

August 29, 2007

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

May 2007

Agenda

- Meeting Objectives
- Introductions
- SIG Meeting Schedule
- Overview of CTMS Workspace
- Overview of Reporting / Sharing SIG
- Clinical Trials Database (CTDB)
- Comment, Feedback, Questions
- Review of Action Items

Meeting Objectives

- Overview of the Clinical Trial Management Systems (CTMS) Workspace
- Overview of the Reporting/Sharing SIG Activities and Projects
- Introduction of the current Reporting/Sharing Task Force
- Overview of the Clinical Trials Database (CTDB)
  - Proposed First Iteration
  - Next Steps

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Introductions

- **SIG Lead:** **Christo Andonyadis**
  NCI Center for Biomedical Informatics and Information Technology (NCI CBIIT)
  andonyac@mail.nih.gov

- **SIG Facilitator:** **Karen Ryan**
  Booz Allen Hamilton (BAH)
  ryan_karen@bah.com

- **SIG Support:** **Ryan Budd**
  Booz Allen Hamilton (BAH)
  budd_ryan@bah.com

Meeting Schedule for SIG

- **All SIG calls are open to the community**
- **Listserv: CABIG_CTMS_REPT_SIG@LIST.NIH.GOV**

Meeting	***Call Schedule***
Reporting/Sharing SIG	4th Wednesday each month; 3:00-5:00pm ET

SIG Meetings

- All SIG meetings are open to the community
- Information on the SIG meetings are posted to the Listserv (https://list.nih.gov/archives/cabig_ctms_rept_sig.html)
- SIG Members are encouraged to provide input and feedback on the projects via the following mechanisms:
  - Participate in SIG calls, Workspace calls and face-to-face meetings
  - Participate in community demonstrations of applications that are under development (announced via the CTMS and SIG Listserv)
  - Contact a Reporting / Sharing Task Force member
  - Contact a Steering Committee member
  - Contact SIG Lead or Facilitator
  - Contact CTMS Workspace Lead

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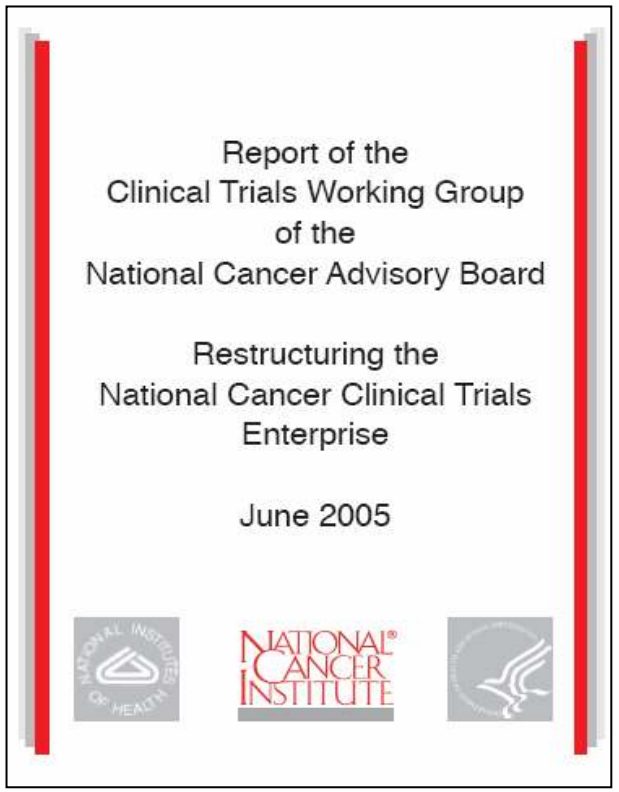
Clinical Trials Working Group

- National Cancer Advisory Board Group
- Report "Re-engineering the Cancer Clinical Research Enterprise" *(June 2005)*
- Remit: advise on *"whether, and in what ways, the NCI-supported national clinical trials enterprise should be restructured to realize the promise of molecular medicine for advancing oncologic clinical practice in the 21st Century"*



Clinical Trials Working Group (CTWG)

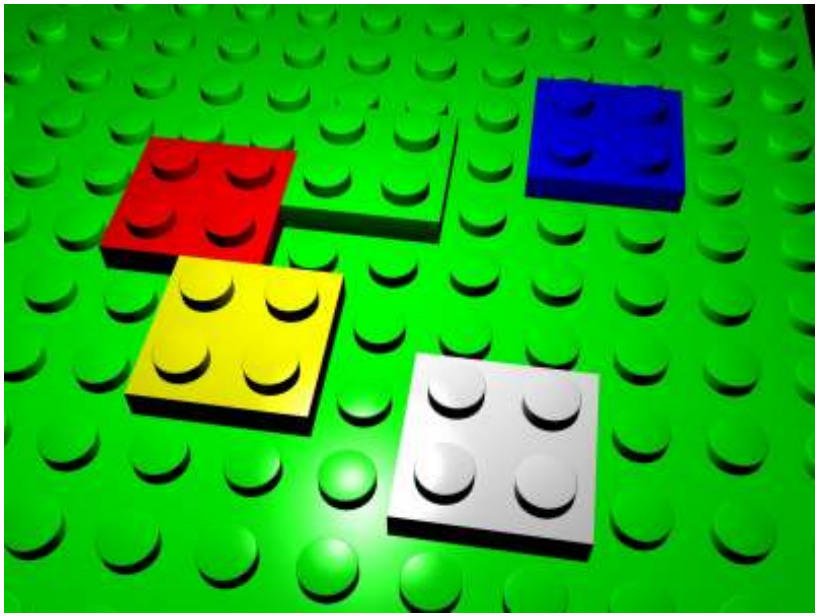
CTWG Goals	CTWG Informatics Initiatives
Enhanced Coordination	Establish a comprehensive database containing regularly-updated information on all NCI-funded clinical trials
Enterprise-wide Standardization	Achieve industry and FDA concurrence on standard Case Report Forms incorporating Common Data Elements
	Promote establishment of national clinical trial information technology infrastructures that are fully interoperable with NCI's cancer Biomedical Informatics Grid (caBIG™)
	Develop a credentialing system for investigators and sites that is recognized and accepted by NCI, industry sponsors, clinical investigators, and clinical trial sites

CTMS Workspace Goals

- **Facilitate the planning and instantiation of clinical trials, (and monitoring of trials once they are instantiated)**
- **Facilitate the conduct of clinical trials**
- **Facilitate the reporting and sharing of clinical trial data to existing/ new destinations**
- **Achieve interoperability**
  - Increase the ability of systems to *access* and *use* the data and functionality of other systems
  - Facilitate the integration of new sources and destinations of data

caBIG™'s Special Sauce: Modularity Implies Interoperability

- **Building for the next ten years: Need to interface rapidly with new data sources and destinations**
- **<u>Only</u> a set of interoperable modules is agile enough to handle the speed of science**
- **Anyone can build a module that plugs in – if they build to published caBIG™ standards**
- **Modularity *<u>implies</u>* interoperability**



CTMS Workspace Organization

Planning/ Monitoring

- Investigator and Site Credential Repository
- Study Initiation Tool
- Protocol Lifecycle Tracking
- FIREBIRD
- DCP/DESK

Study Conduct

- Standardized Case Report Forms
- Cancer Central Clinical Database (C3D)
- Participant Registry
- Laboratory Interface
- Financial/Billing
- Study Calendar
- Subject Prescreening
- Vendor Systems

Reporting/ Sharing

- Clinical Trials Database
- Routine Data Exchange
- Clinical Trials Object Model (CTOM)
- Janus (FDA Repository)
- Adverse Event Reporting and Collection (caAERS)
- AE Expedited Reporting (AdEERS)
- Clinical Data System (CDS)

Interoperability

- System Interoperability and Harmonization
- Biomedical Research Integrated Domain Group (BRIDG) model
- caBIG™ Clinical Trials Suite (Clinical Trials Interoperability Project)

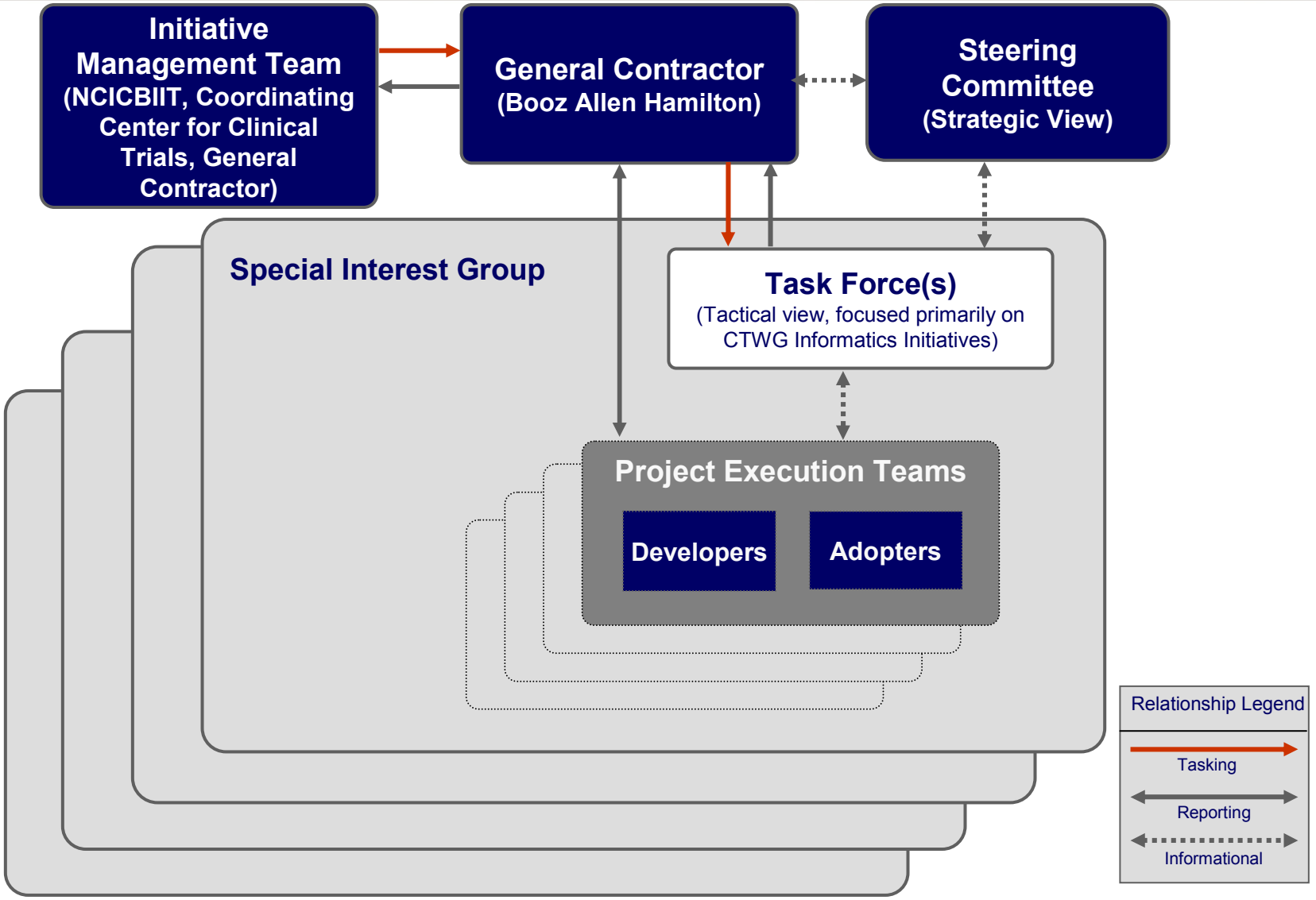
CTMS SIGs: Telcon Schedule and Listservs

SIG	Teleconference	Listserv (http://list.nih.gov)
Planning / Monitoring	3rd Tuesdays 2:00 – 4:00 PM EDT	CABIG_CTMS_PLAN_SIG@LIST.NIH.GOV
Study Conduct	3rd Wednesdays 3:00 – 5:00 PM EDT	CABIG_CTMS_COND_SIG@LIST.NIH.GOV
Reporting / Sharing	4th Wednesdays 3:00 – 5:00 PM EDT	CABIG_CTMS_REPT_SIG@LIST.NIH.GOV
Interoperability	4th Tuesdays 2:00 – 4:00 PM EDT	CABIG_CTMS_INTR_SIG@LIST.NIH.GOV

CTMS SIG Listservs: How To Subscribe

- Browse lists at NIH Listserv List page https://list.nih.gov/cgi-bin/show_list_archives).
- Select Listserv of choice
- Click on “Join or leave the list, or update options”
- Enter Email address and full name and click on “Join the List.”
- Upon receipt of confirmation Email, click on link provided within the Email to finalize subscription.
- To unsubscribe from any list, please visit the NIH Listserv List page and click on the specific listserv link. Click on “Leave the List”, enter email address and full name, and click on “Leave the List.”

CTMS Workspace Management



CTMS Web Page
https://cabig.nci.nih.gov/workspaces/CTMS

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Reporting / Sharing SIG

Planning/ Monitoring

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Study Conduct

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Interoperability

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- Biomedical Research Integrated Domain Group (BRIDG) model
- caBIG™ Clinical Trials Suite (Clinical Trials Interoperability Project)

Reporting / Sharing Task Force Members *(Current)*

James Anderson, Ph.D.	University of Nebraska
Rhoda Arzoomanian, R.N.	University of Wisconsin
Dawn Caron-Fabio	Memorial Sloan-Kettering Cancer Center
John Ellerton, M.D.	Nevada Community Clinical Oncology Program
Shanda Finnigan, R.N.	NCI Cancer Therapy Evaluation Program (CTEP)
Steve Friedman	NCI Cancer Therapy Evaluation Program (CTEP)
Lakshmi Grama	NCI Office of Communication and Education
Tad McKeon	St. Jude Children's Research Hospital
Randy Millikan, M.D., Ph.D.	MD Anderson
Bob Morrell	Wake Forest University
Diane Paul	Consumer Advocates in Research and Related Activities (CARRA)
George Redmond	NCI Cancer Therapy Evaluation Program (CTEP)
Ann Setser, R.N.	NCI Cancer Therapy Evaluation Program (CTEP)
Anne Tompkins, R.N.	NCI Division of Cancer Prevention (DCP)
Brenda Young, R.N.	American College of Radiology
Jamie Zwiebel, M.D.	NCI Cancer Therapy Evaluation Program (CTEP)

Clinical Trials Database (CTDB)

Clinical Trials Working Group Informatics Initiative

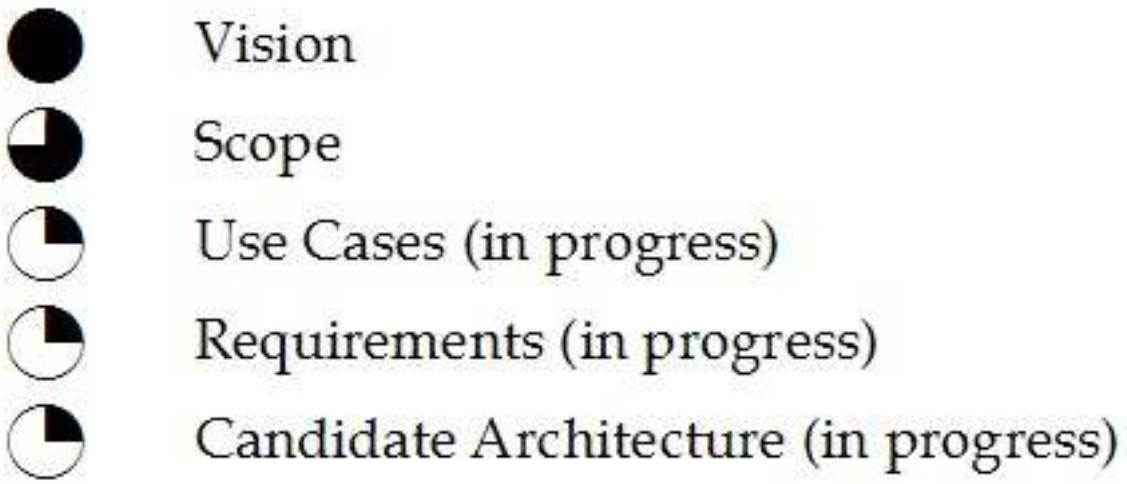
- A comprehensive, community accessible database that will contain complete, up-to-date information (e.g., status, protocol, accrual, adverse events, toxicity, efficacy) on all NCI-supported clinical trials
  - Prioritization enhanced, duplication of effort reduced by full picture of cancer clinical trials enterprise
  - Patient accrual enhanced through better physician/patient access to clinical trials data
  - Rapid dissemination of toxicity / adverse event information
  - Rapid dissemination of patterns of favorable outcomes
- Designed and implemented in accordance with caBIG™ principles / standards
- NCI Center for Biomedical Informatics and Information Technology will design data submission procedures in consultation with NCI program staff and representatives of the extramural community
- Long-term goal: include information on trials funded by other public- and private-sector sponsors

Pilot CTDB SIG

- **Initiated June 2006**
- **Reviewed scope**
- **Architectural options**
  - Central
  - Distributed
  - Hybrid
- **Suspended October 2006**
- **caBIG CTMS Restructuring**
- **Proposed first (central) iteration**
  - Register all trials
    - Including protocol document
    - Classification to support Summary 4 reporting
  - Accrual data
    - CDUS Abbreviated style
  - Built on top of CTOM for easy extension

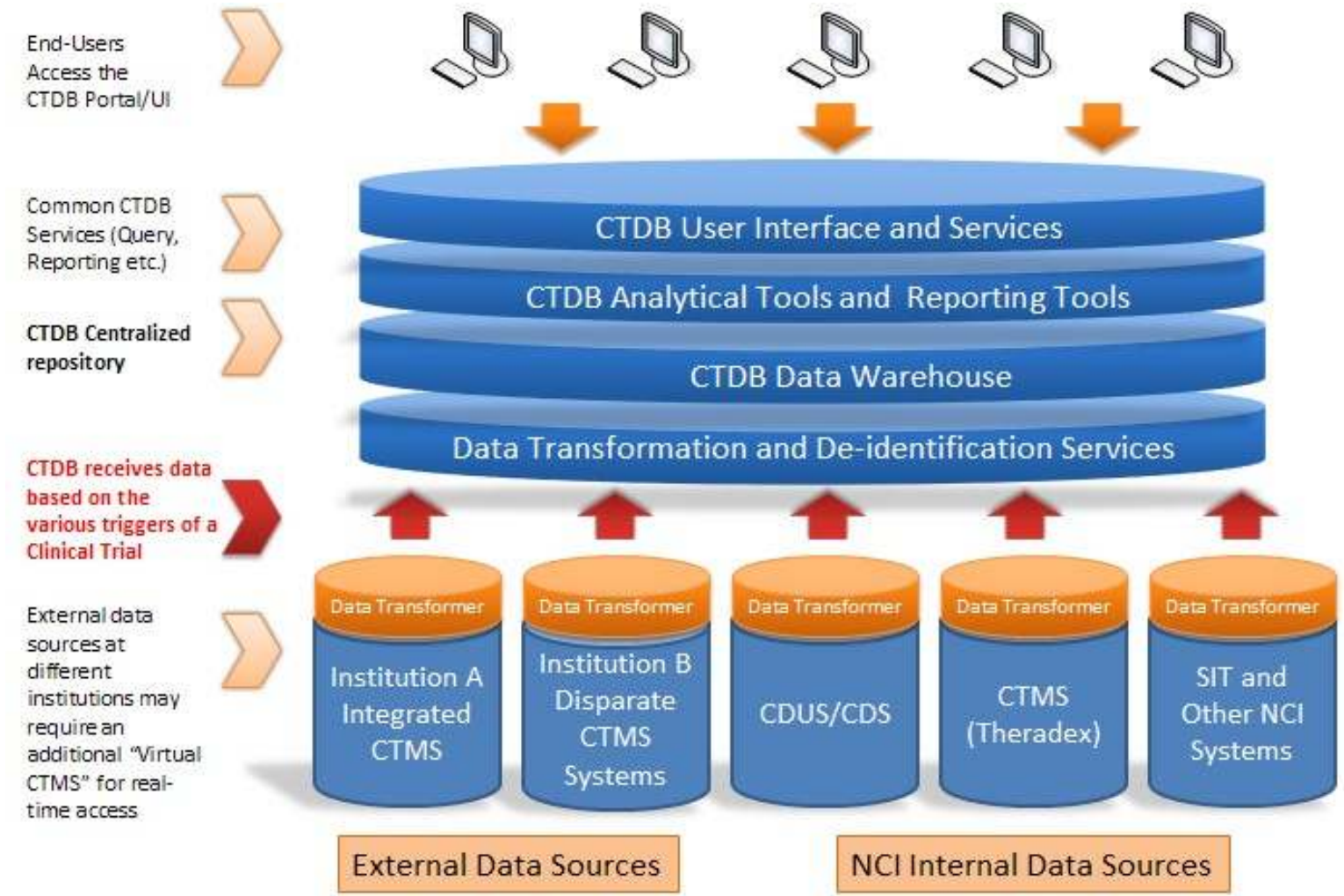
Pilot CTDB SIG Activities

The SIG completed the following key Inception activities:



Development and refinement of Use Cases, Requirements and Candidate Architecture are conducted in an iterative fashion. The CTDB SIG in conjunction with the CTDB Project Team has completed an initial pass through the Use Cases, Requirements and Candidate Architecture.

Centralized Candidate CTDB Architecture



Routine Data Exchange – Pilot SIG

- **Defining the requirements for a regulatory reporting interface module that will facilitate the submission of clinical trial reports electronically to NCI's CDUS (Clinical Data Update System) and the NCI's Clinical Trial Monitoring Service (CTMS).**
- **Capture relevant data from multiple systems and in multiple formats and translate them into the required formats. The process will be automated as much as possible to improve workflow and minimize manual operations.**
- **Allows retention of data that is lost under current reporting mechanisms to improve and facilitate internal analysis of ongoing studies.**

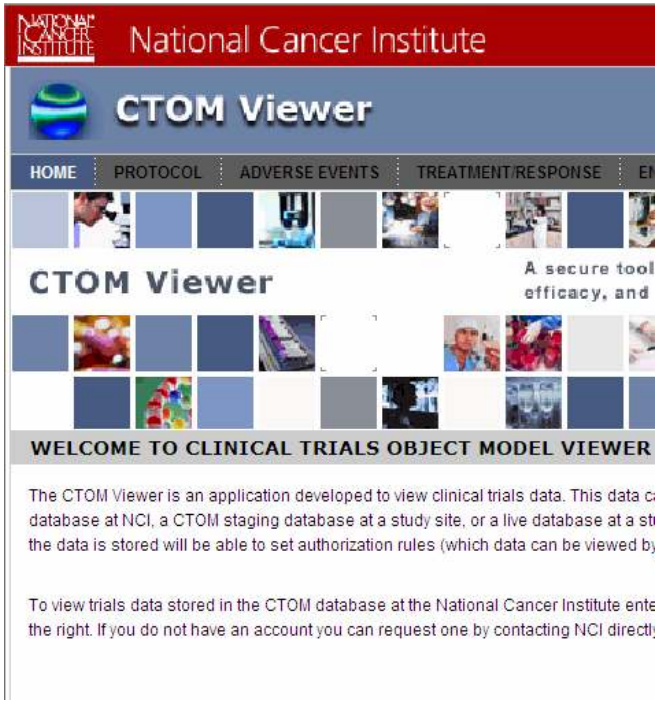
RDX Activities

- **Reporting Recommendations Whitepaper**
  - Clinical Trials Monitoring Service (CTMS) and Clinical Data Update System (CDUS) data elements (CDEs) should be harmonized
  - Support for cumulative as well as incremental updates
    - CTMS currently supports only incremental
    - CDUS currently supports only cumulative
  - Submitted data available made available in standard reports
  - Data should be sent securely
- **Summary 3 & 4 Issues**
  - Proposed definition of “Therapeutic Trial”
    - ***Those trials in which a study agent, device or other intervention is used with the intention of curing or preventing disease or prolonging or otherwise improving the life of the subject on the trial.***
  - Disease Site list should include all ICD-O

Summary 4 Columns

- Group/Sponsor/Funding Source
- Anatomic Site (Site)
- Protocol ID/IRB Number
- Principal Investigator (PI)
- Program (Prog) – as defined in Summary 1B
- Date Opened - opened to accrual or initiated
- Date Closed -closed to accrual or completed
- Phase - pilot, feasibility, 1, 2, 3,4, or combinations such as ½ and N/A
- Trial/Study Type (Type)
  - Therapeutic intervention (Ther)
  - Prevention intervention (Prev)
  - Screening, Early Detection, or Diagnostic (Screen, Detect, Diag)
  - Supportive Care (Supp)
  - Epidemiologic/Observational (Epi,Obs)
  - Ancillary or Companion (Anc, Comp)
  - Correlative (Corr)
- Title
- Target Accrual
- Accrual Site – Center and Other
- Accrual Timeframes – 12 months and To Date

Clinical Trials Object Model (CTOM)



- **CTOM is a common model of clinical trials data**
  - **Focused on outcomes**
  - **Assessments, observations and findings**
  - **BRIDG harmonized**
- **Standardize on the model, not the database**
- **CTOM uses caBIG technology (caAdapter, caCORE SDK generated Java Application Program Interfaces) to support:**
  - **Mapping of local data sources to CTOM**
  - **Sharing of local data via CTOM APIs**
- **CTOM APIs have already been mapped to:**
  - **CTOM database**
  - **Janus database**
- **CTOM Viewer uses CTOM APIs to access data**
- **CTOM database populated with CTMS/Theradex data files**

FDA's JANUS Submission Data Repository Model

Janus

- **Original concept and design by Norman Stockbridge and Jonathan (Jay) Levine of FDA/CDER, 1999.**
- **Lincoln Technologies developed an early prototype implementation in 2001.**
- **Key concepts integrated into CDISC data standardization efforts, leading to release of SDTM 1.0 and Implementation Guide 3.1 in July 2004.**
- **FDA and IBM designed the current Janus clinical data submission repository**
  - Worked under a Cooperative R&D Agreement (CRADA), completed in 2004
  - Janus logical data model published: http://www.fda.gov/oc/datacouncil/
- **IBM implemented a Janus prototype for FDA and NCI**
  - FDA and NCI cooperating through an Interagency Oncology Task Force (IOTF)
  - Testing completed in January 2006
- **IBM is currently implementing a Janus Operational Prototype for FDA and NCI**

Janus Vision

- **An infrastructure that will:**
  - allow secure transmission of clinical research information between sponsors, researchers, and regulatory authorities;
  - facilitate the adoption of electronic data standards, standardized terminologies, e-transactions, and e-submissions;
  - reduce the overall cost of existing information gathering and submissions development processes as well as review and analysis of information; and
  - be accessible to all.

High Level Architecture
Operational Prototype for FDA

System Admin

Accept / Reject Status Feedback

Review & Analysis Tools
(WebSDM, I/J-Review, SAS, S+)

Application Integration Framework
(SDTM Materialized Views)

EDR

Submission Data
(SDTM 3.1 and 3.1.1)

SDTM Validation

"Valid" SDTM Data"

Staging Area

"Valid" SDTM Data"

Load Scripts

Janus
(Hosted at NCI)

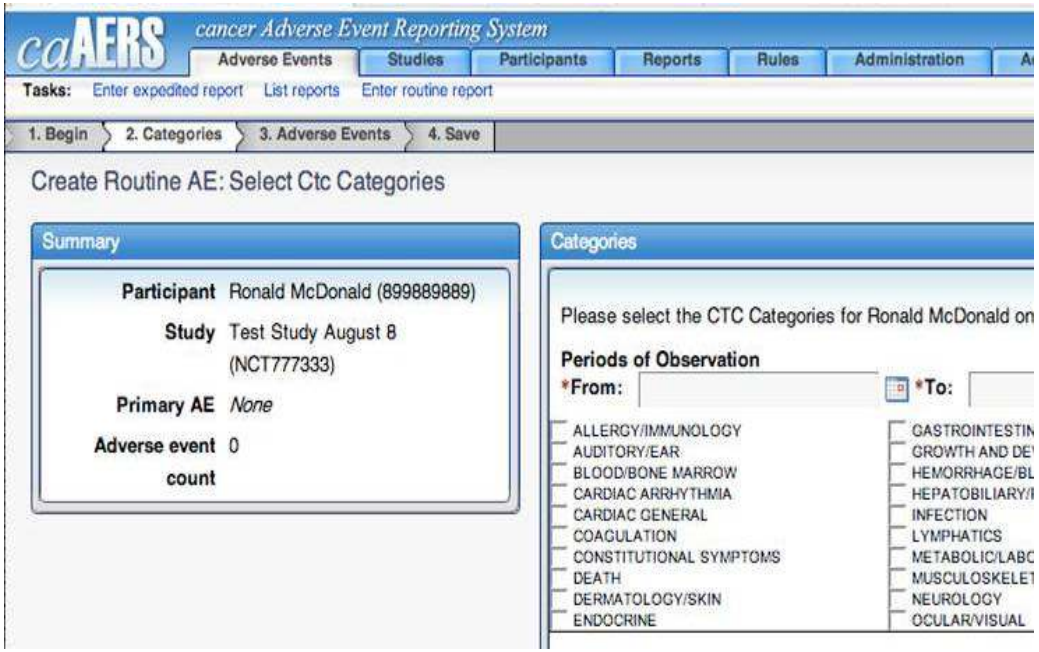
Success / Failure Status Feedback

Data Validation (WebSDM)

Cancer Adverse Event Reporting System (caAERS)

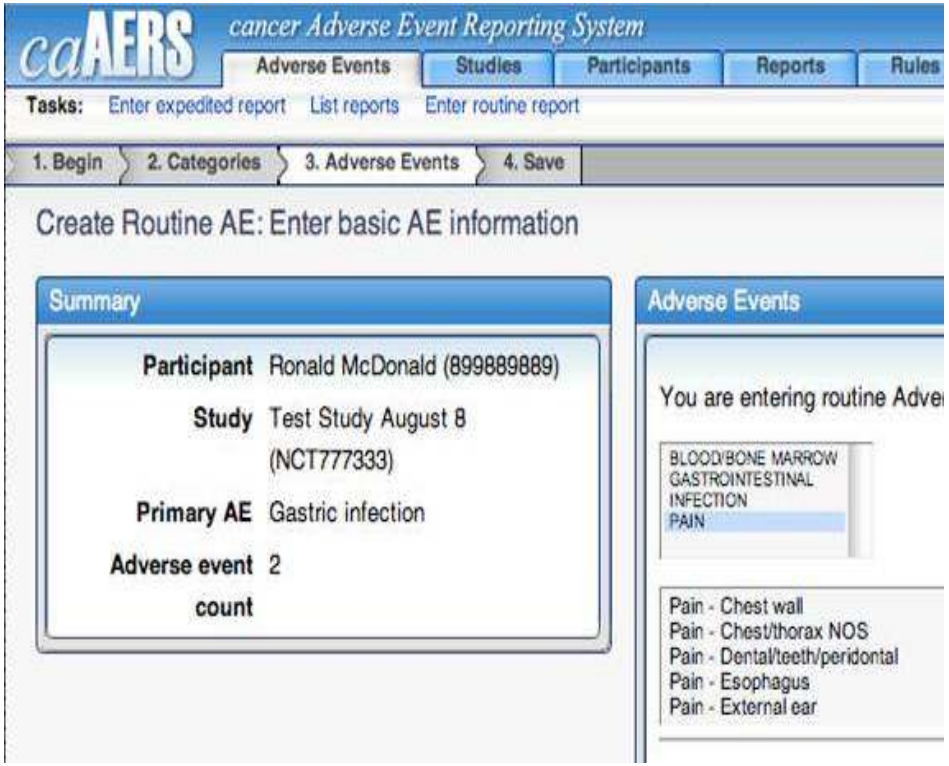
- **Module 1: Adverse Event Data Capture**
  - **Information entered through a web interface, the system captures the severity of the adverse event and provides instructions for further reporting**
  - **Internal reporting capabilities allow the CRA to follow submissions, Quality Assurance to review them, and the Principal Investigator(s) to monitor toxicities and address further reporting requirements**

- **Module 2: Interface between AE Capture Tool & Local Clinical Trials Databases**
  - **Facilitates communication between module 1 database and the participating institution's clinical trials database**

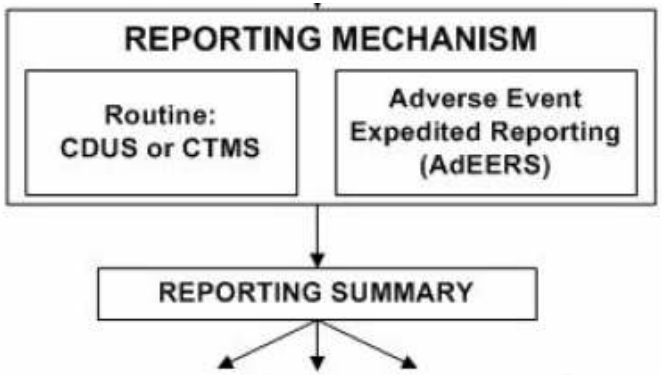


Cancer Adverse Event Reporting System (caAERS)

- **Module 3: Vocabulary Mapping Service**
  - **Utilizes mappings from the CTMS Metadata/Vocabulary project to support customized reports and forms**
  - **Common Toxicity Criteria (CTC)/MedDRA mappings supported in searches on AE category and term during data capture and for reporting**
- **Module 4: External Agency Reporting**
  - **Expanded functionality for electronically communicating SAEs to participating entities/systems such as AdEERS**
  - **Provides generic alert messages to national cooperative groups and industrial sponsors involved with NCI funded protocols**



CTEP Adverse Event Reporting



ATTRIBUTION	GRADE 1		GRADE 2		GRADE 3		GRADE 4		GRADE 5	
	UNEXPECTED	EXPECTED	UNEXPECTED	EXPECTED	UNEXPECTED	EXPECTED	UNEXPECTED	EXPECTED	UNEXPECTED	EXPECTED
UNRELATED	CTMS	CTMS	CTMS	CTMS	CTMS CDUS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS
UNLIKELY	CTMS	CTMS	CTMS	CTMS	CTMS CDUS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS
POSSIBLE	CTMS CDUS	**CTMS CDUS**	CTMS CDUS AdEERS	**CTMS CDUS**	CTMS CDUS AdEERS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS
PROBABLE	CTMS CDUS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS
DEFINITE	CTMS CDUS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS

CDUS – CLINICAL DATA UPDATE SYSTEM for Routine Reporting

CTMS – CLINICAL TRIALS MONITORING SERVICE for Routine Reporting

AdEERS – EXPEDITED REPORTING (This includes hospitalization [or prolongation of existing hospitalization] for any event equivalent to CTC Grade 3, 4, 5 which precipitated hospitalization regardless of requirements for Phase of study, expected or unexpected, and attribution.)

Phase 1 Trials AdEERS Reporting Timelines

3.4.1 Phase 1 Trials utilizing an Agent under a CTEP IND: AdEERS Expedited Reporting Requirements for Adverse Events that occur within 30 Days of the Last Dose of the Investigational Agent

Table C: Reporting Requirements for Adverse Events that occur within 30 Days[1] of the Last Dose of the Investigational Agent on Phase 1 Trials

	1	2	2	3		3		4 & 5[2]
	Unexpected and Expected	Unexpected	Expected	Unexpected		Expected		Unexpected and Expected
				with Hospitalization	without Hospitalization	with Hospitalization	without Hospitalization	
Unrelated Unlikely	Not Required	Not Required	Not Required	10 Calendar Days	Not Required	10 Calendar Days	Not Required	24-Hour; 5 Calendar Days
Possible Probable Definite	Not Required	10 Calendar Days	Not Required	24-Hour; 5 Calendar Days	24-Hour; 5 Calendar Days	10 Calendar Days	Not Required	24-Hour; 5 Calendar Days

[1]**Adverse events with attribution of possible, probable, or definite that occur greater than 30 days after the last dose of treatment with an agent under a CTEP IND require reporting as follows:**

AdEERS 24-hour notification followed by complete report within 5 calendar days for:

- Grade 3 unexpected events with hospitalization or prolongation of hospitalization
- Grade 4 unexpected events
- Grade 5 expected and unexpected events

[2]Although an AdEERS 24-hour notification is not required for death clearly related to progressive disease, a full report is required as outlined in the table.

December 15, 2004

Phase 2 & 3 Trials AdEERS Reporting

3.4.2 Phase 2 and Phase 3 Trials utilizing an Agent under a CTEP IND: AdEERS Expedited Reporting Requirements for Adverse Events that occur within 30 Days of the Last Dose of the Investigational Agent

Table D: Reporting Requirements for Adverse Events that occur within 30 Days[1] of the Last Dose of the Investigational Agent on Phase 2 and 3 Trials

	1	2	2	3		3		4 & 5	4 & 5[2]
	Unexpected and Expected	Unexpected	Expected	Unexpected		Expected		Unexpected	Expected
				with Hospitalization	without Hospitalization	with Hospitalization	without Hospitalization		
Unrelated Unlikely	Not Required	Not Required	Not Required	10 Calendar Days	Not Required	10 Calendar Days	Not Required	10 Calendar Days	10 Calendar Days
Possible Probable Definite	Not Required	10 Calendar Days	Not Required	10 Calendar Days	10 Calendar Days	10 Calendar Days	Not Required	24-Hour; 5 Calendar Days	10 Calendar Days

[1]**Adverse events with attribution of possible, probable, or definite that occur greater than 30 days after the last dose of treatment with an agent under a CTEP IND require reporting as follows:**

AdEERS 24-hour notification followed by complete report within 5 calendar days for:

- Grade 4 and Grade 5 unexpected events

AdEERS 10 calendar day report:

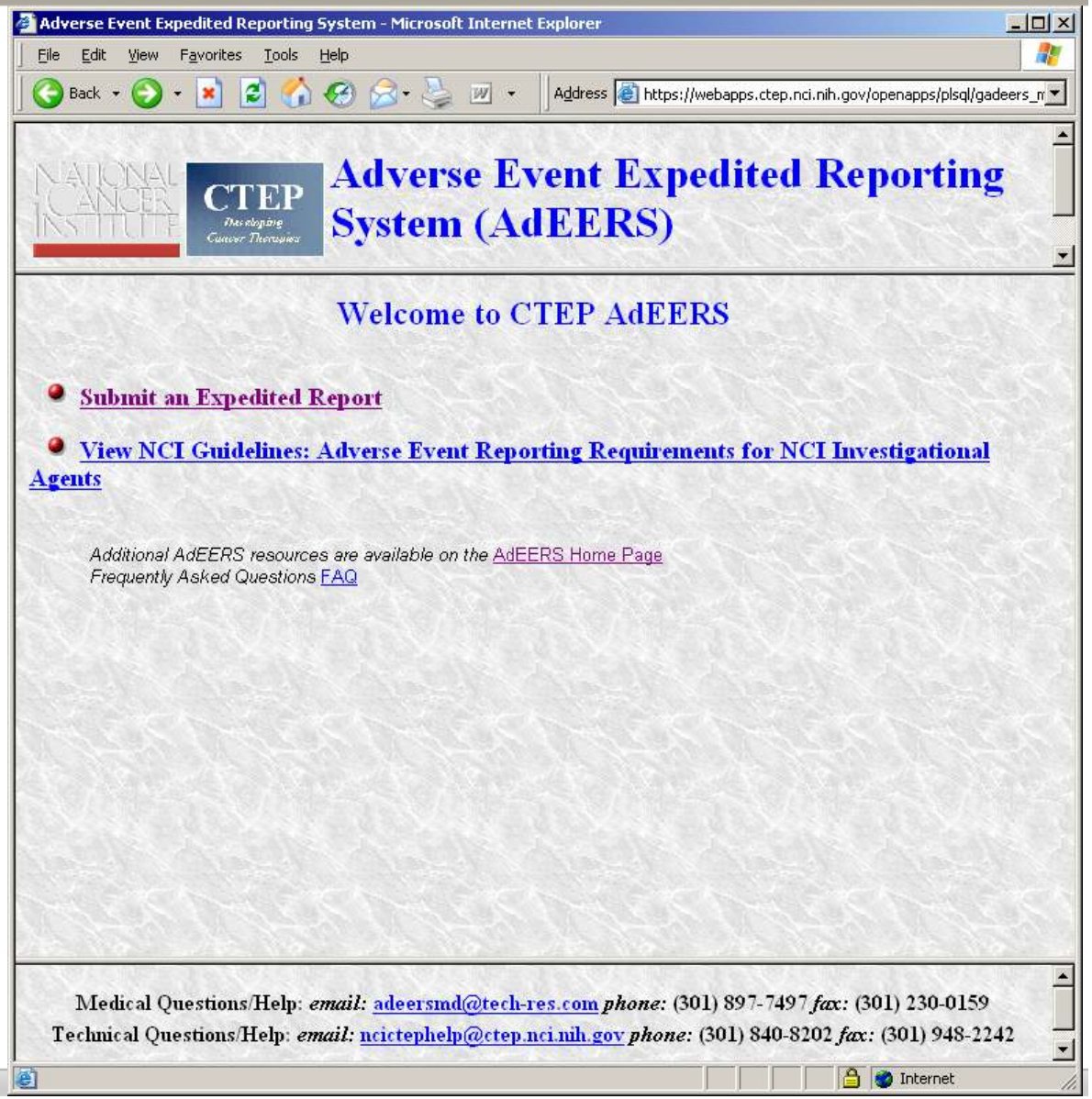
- Grade 3 unexpected events with hospitalization or prolongation of hospitalization
- Grade 5 expected events

[2]Although an AdEERS 24-hour notification is not required for death clearly related to progressive disease, a full report is required as outlined in the table.

December 15, 2004

CTEP Adverse Events Reporting

- **Methods of Submission**
  - AdEERS Website
  - AdEERS Web Service (coming soon!)



Clinical Data Update System (CDUS)

- **Quarterly cumulative submission**
- **Methods**
  - **CTEP FTP Site**
  - **Clinical Data System (CDS) Web interface**
- **Abbreviated**
  - **Protocol administrative data**
  - **Patient accrual information**
  - **Patient demographic information**
- **Complete = Abbreviated +**
  - **Prior therapy, baseline abnormalities**
  - **Treatment status & information** (e.g., agent administered, total dose per course)
  - **Adverse event information** (e.g., AE type, grade)
  - **Response information** (e.g., response observed, date response observed)

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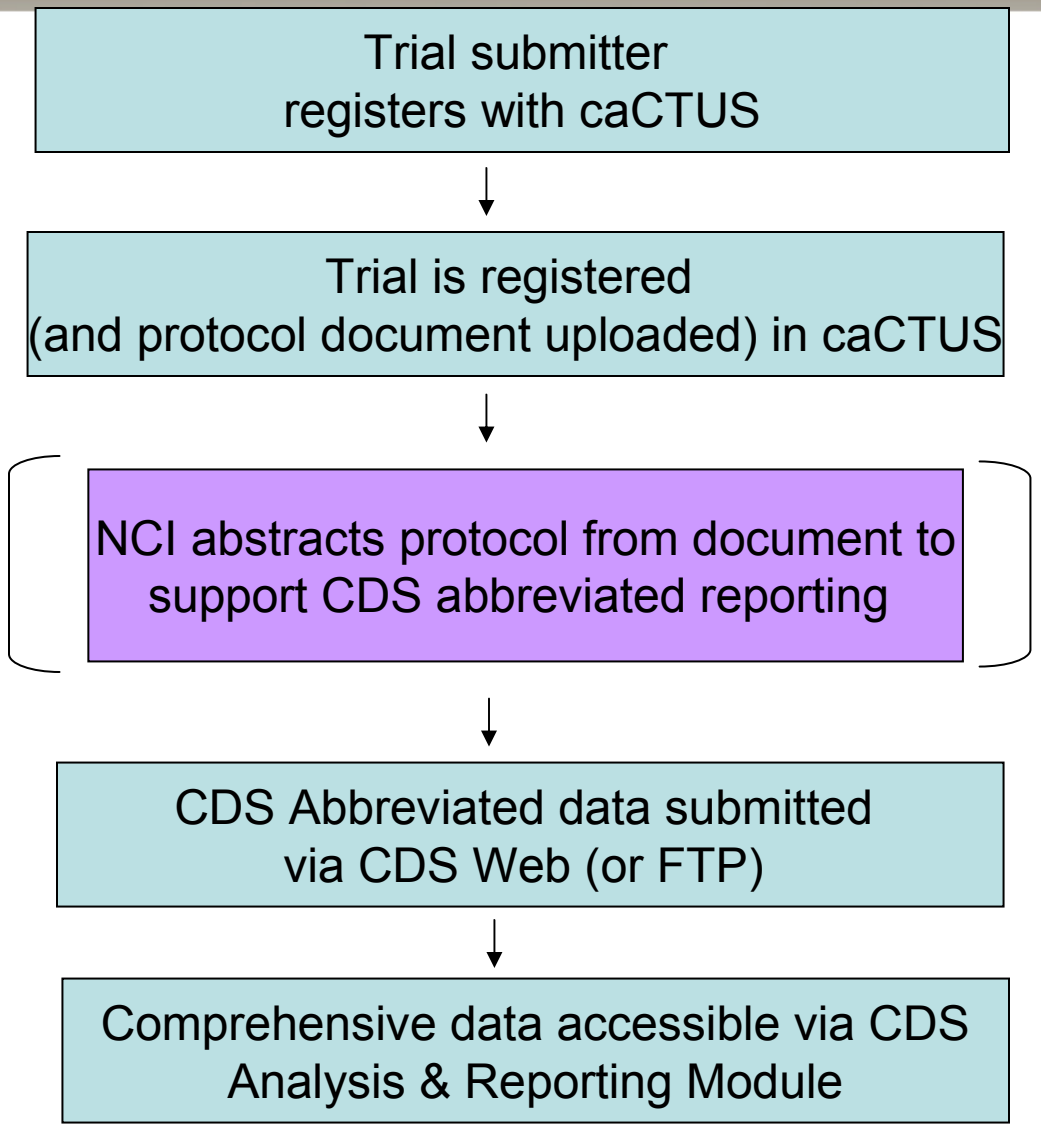
Proposed First Iteration of CTDB

- **Establish central (NCI hosted) database for:**
  - Register all trials (and amendments)
  - Regularly submit accrual and demographic data
- **Provide access to data and reporting to authorized users**
- **Eliminate redundant reporting**
  - Generate Summary 4
  - Report to PDQ
  - Report to ClinicalTrials.gov

Proposed First Iteration of CTDB



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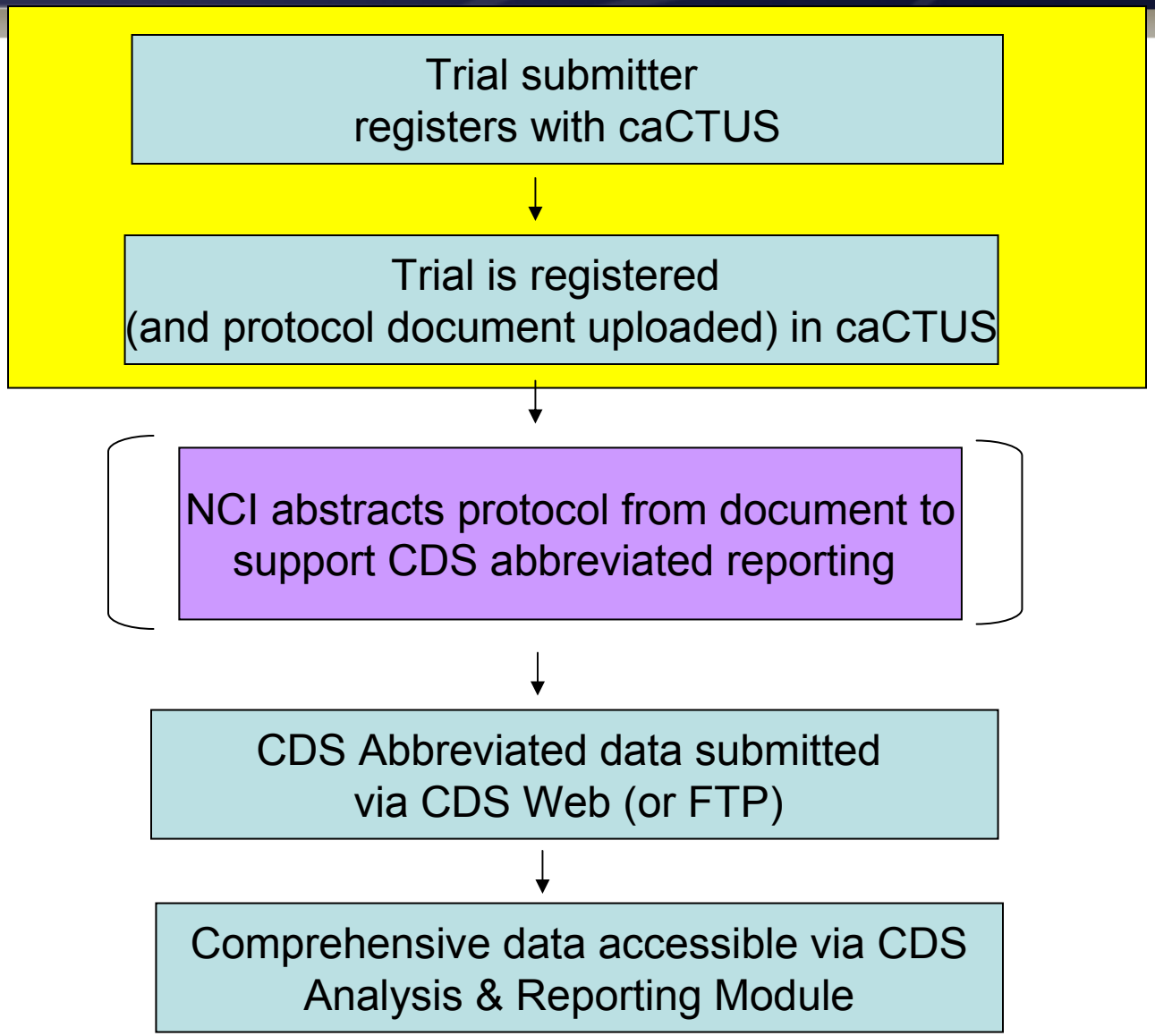
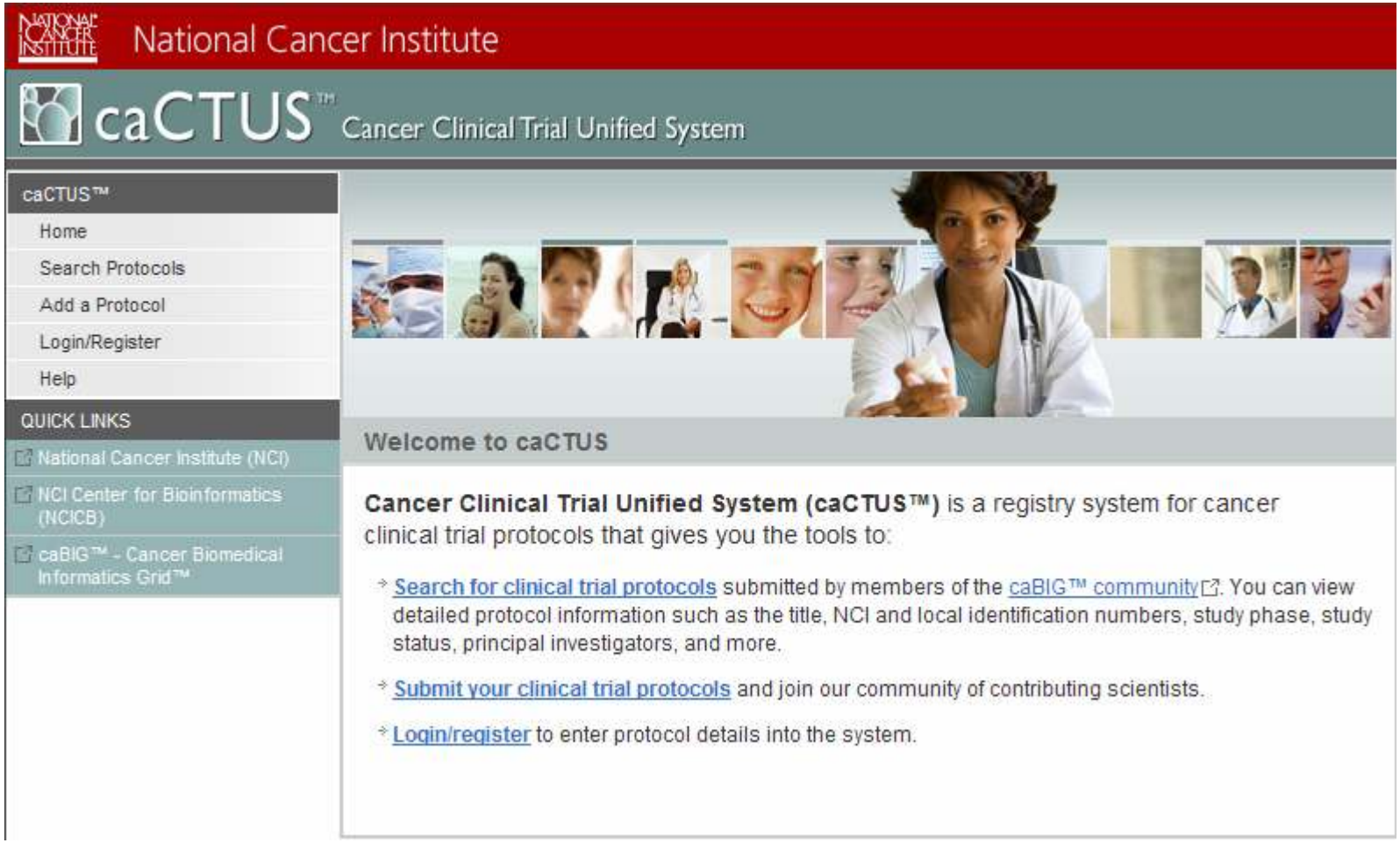
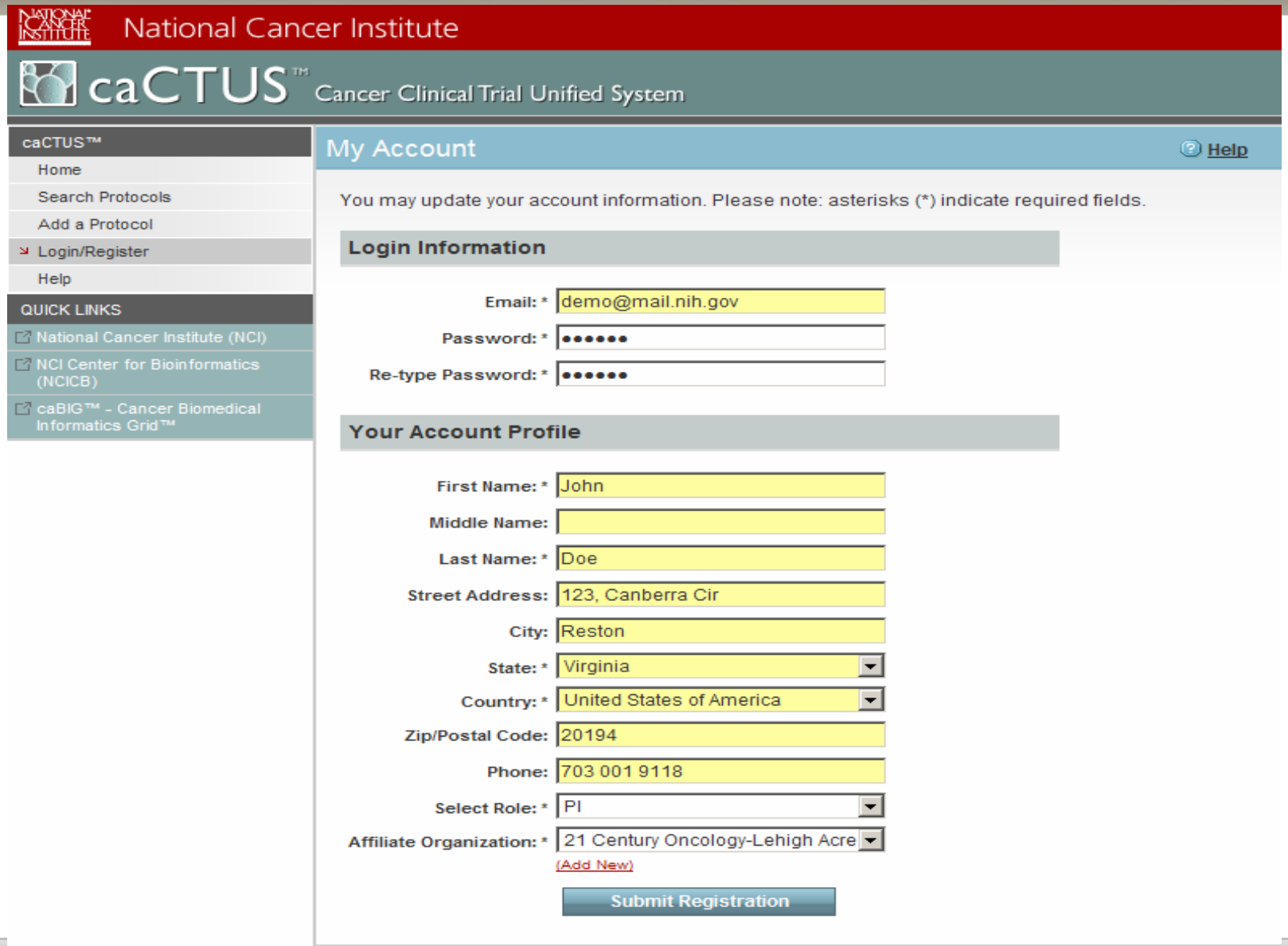


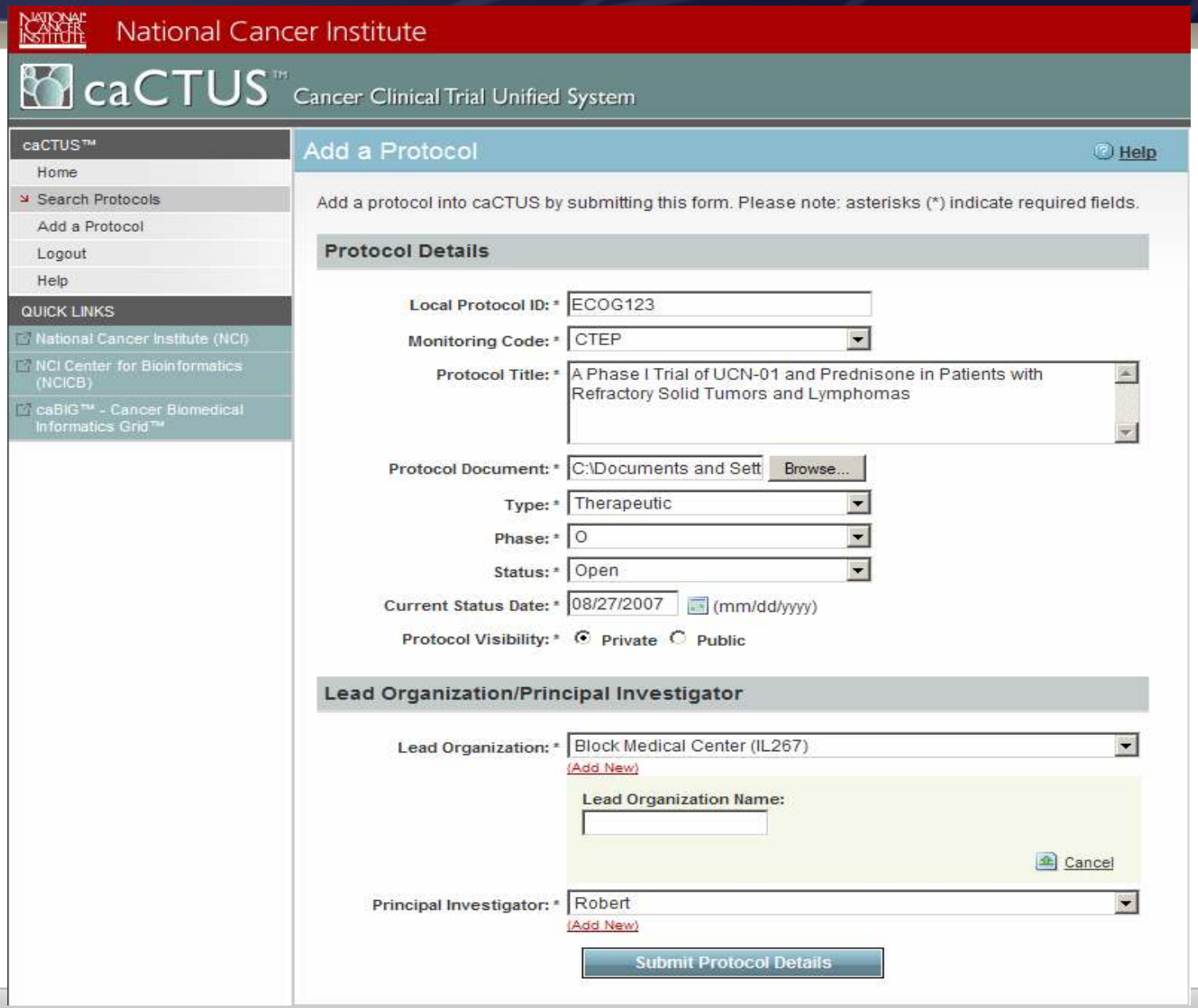
Cancer Clinical Trial Unified System



Submitter Self Registration – Instant Access



Trial Registration and Protocol Document Upload

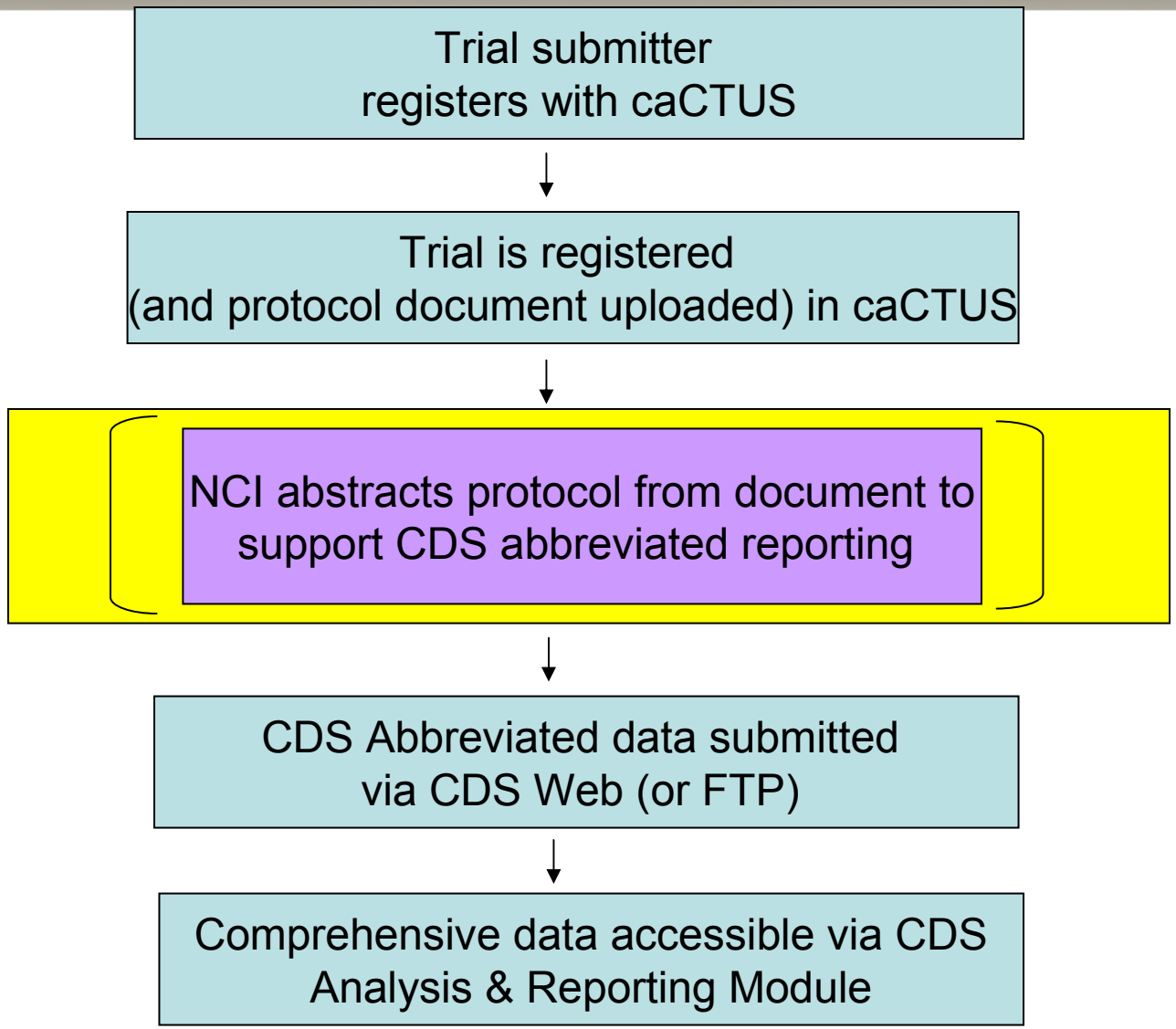


caCTUS Protocol Registration Data Elements (Current – subject to curation)

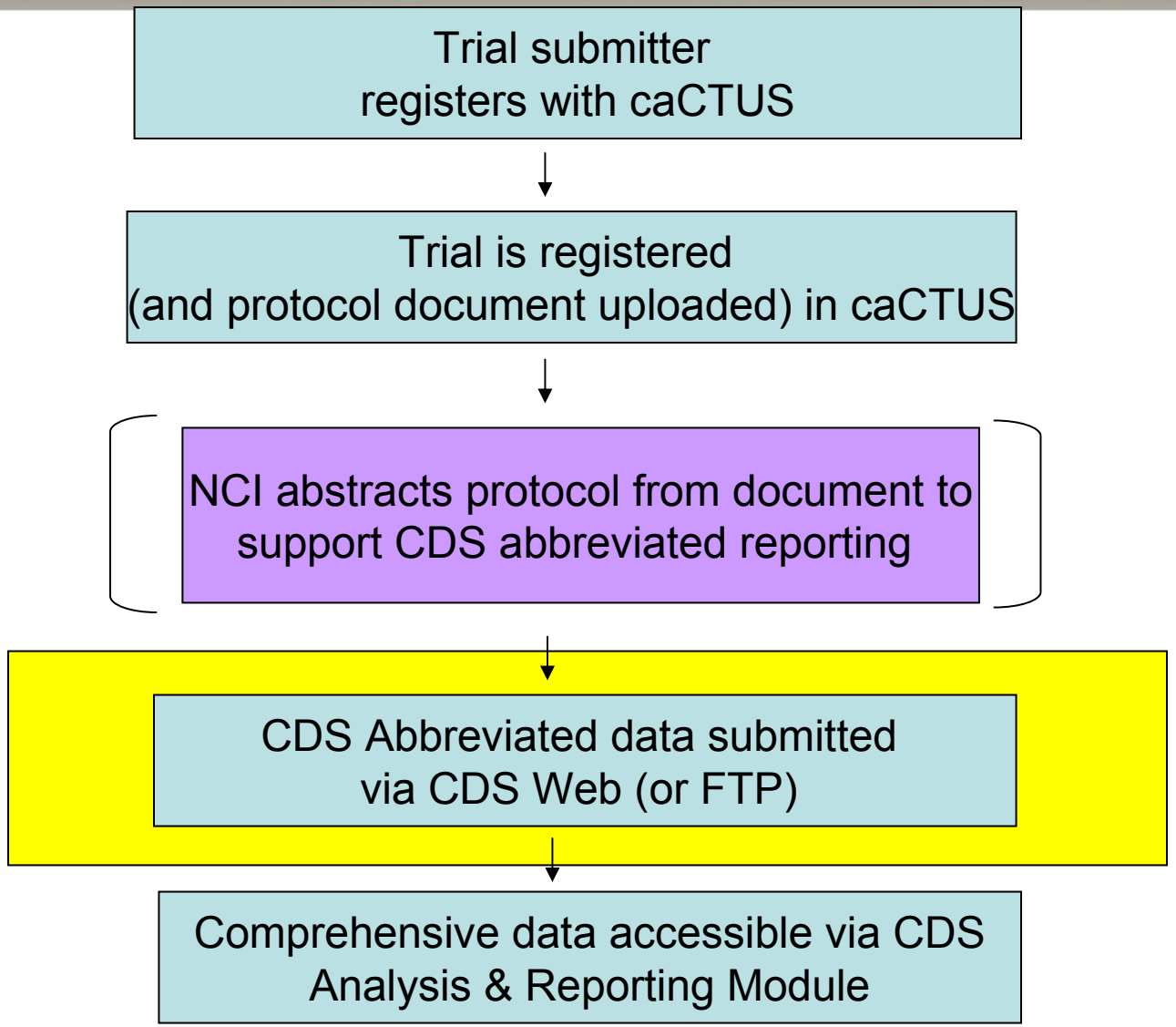
- Local Protocol ID (CDE ID: 2003300)
- Monitoring Code (CDE ID: 2182974)
- Protocol Title (CDE ID: 2182451)
- Protocol document – this is the actual document
- Trial Type (CDE ID: 2675107)
- Trial Phase (CDE ID: 2183023)
- Current Status (CDE ID: 2183054)
- Current Status date (CDE ID: 2608320)
- Lead Organization (CDE ID: 2152)
- Principal Investigator (CDE ID: 2183587 & 2183589)

caCTUS CDEs in caDSR

Proposed First Iteration of CTDB



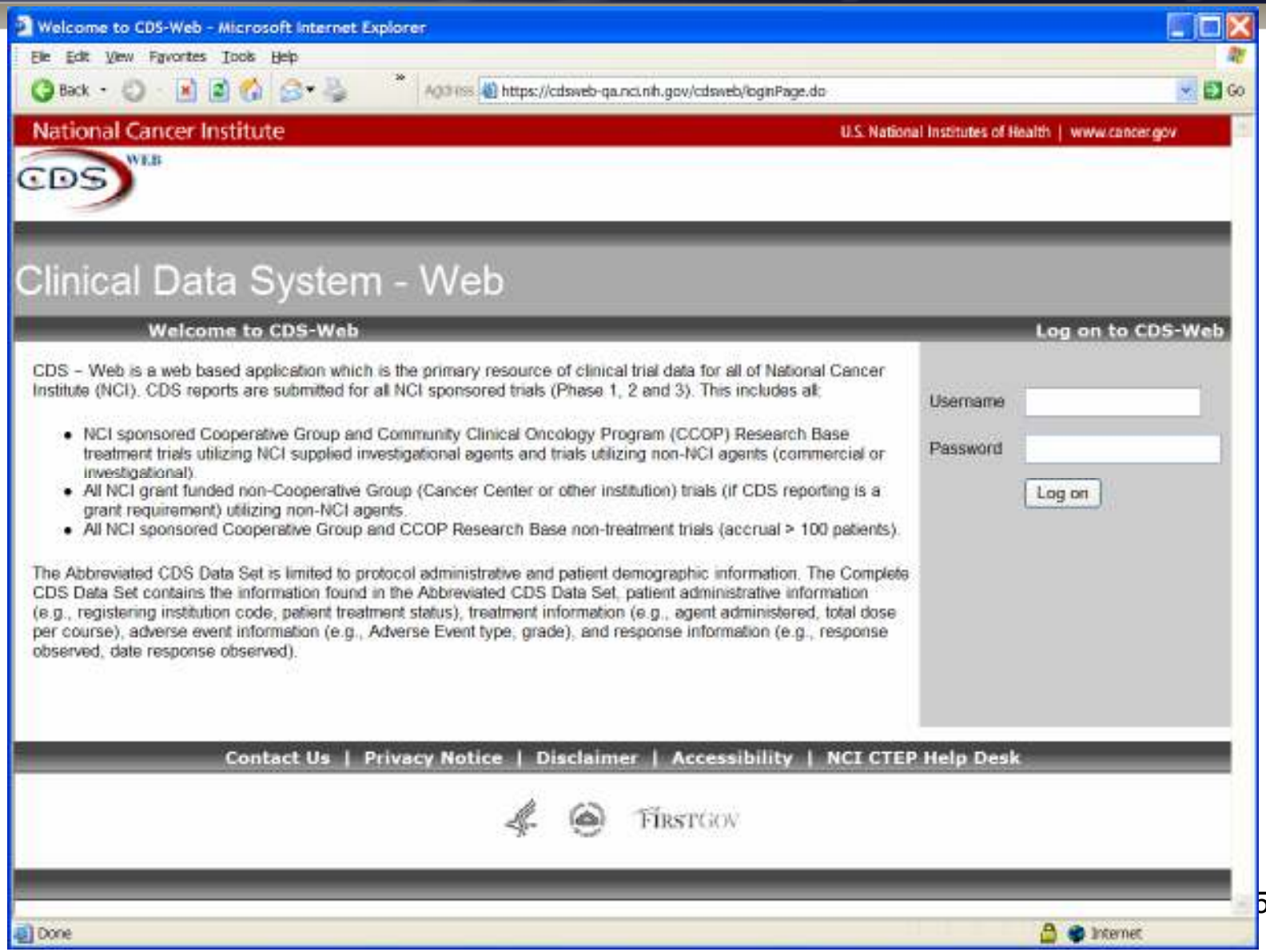
Proposed First Iteration of CTDB



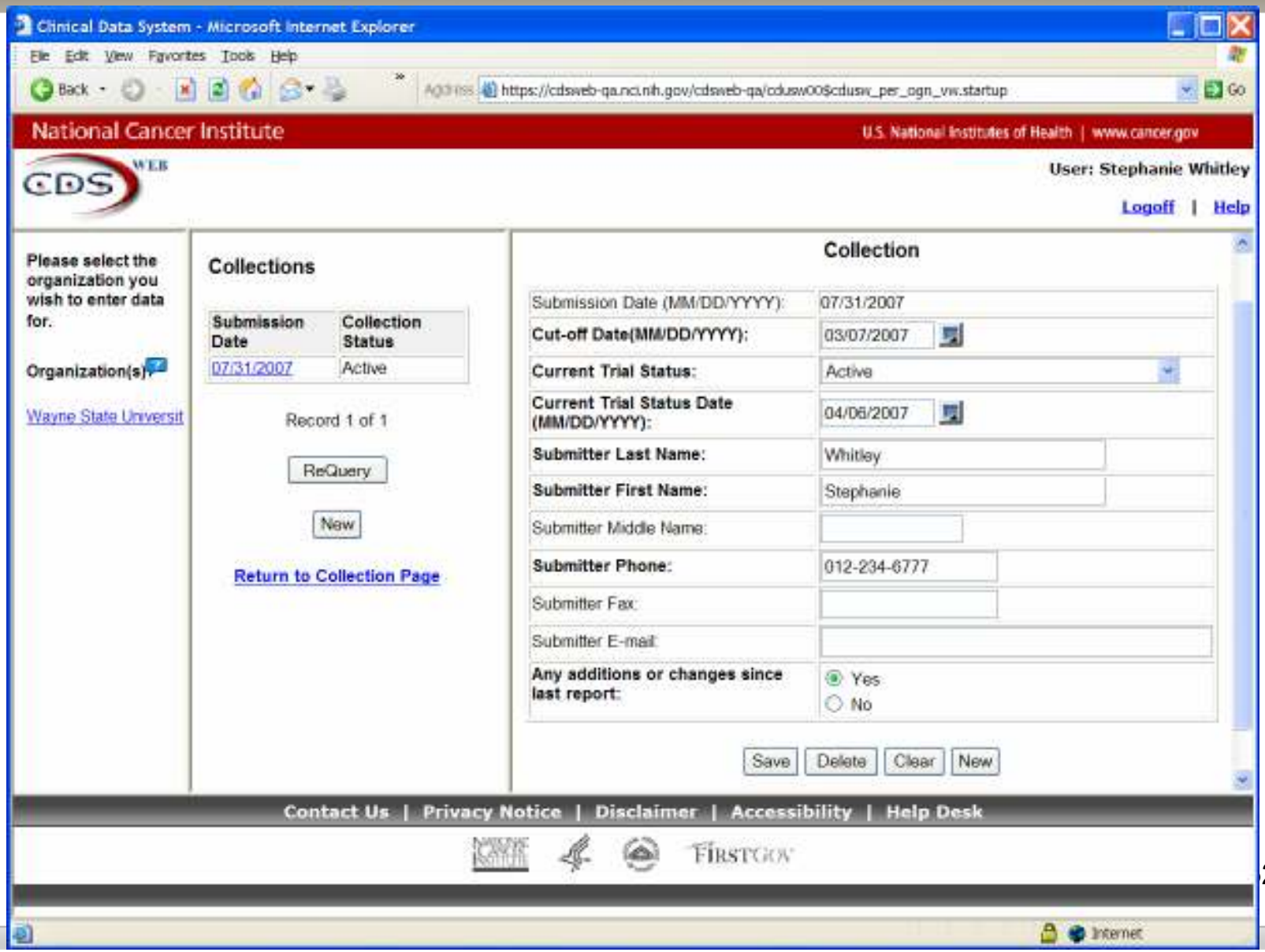
CDUS Abbreviated Submission

- **An Abbreviated CDUS Data Set includes the following data elements:**
  - Protocol Status
    - NCI Protocol Number
    - Current Protocol Status
    - Current Protocol Status Date
  - Patient Accrual/Admin
    - Patient ID
    - Patient's Zip Code
    - Patient's Country Code
    - Patient's Birth Date
    - Patient's Gender
    - Patient's Ethnicity
    - Patient's Method of Payment
    - Date of Patient Entry
    - Registering Group Code (all studies with Group participation)
    - Registering Institution Code (mandatory as of April 1999)

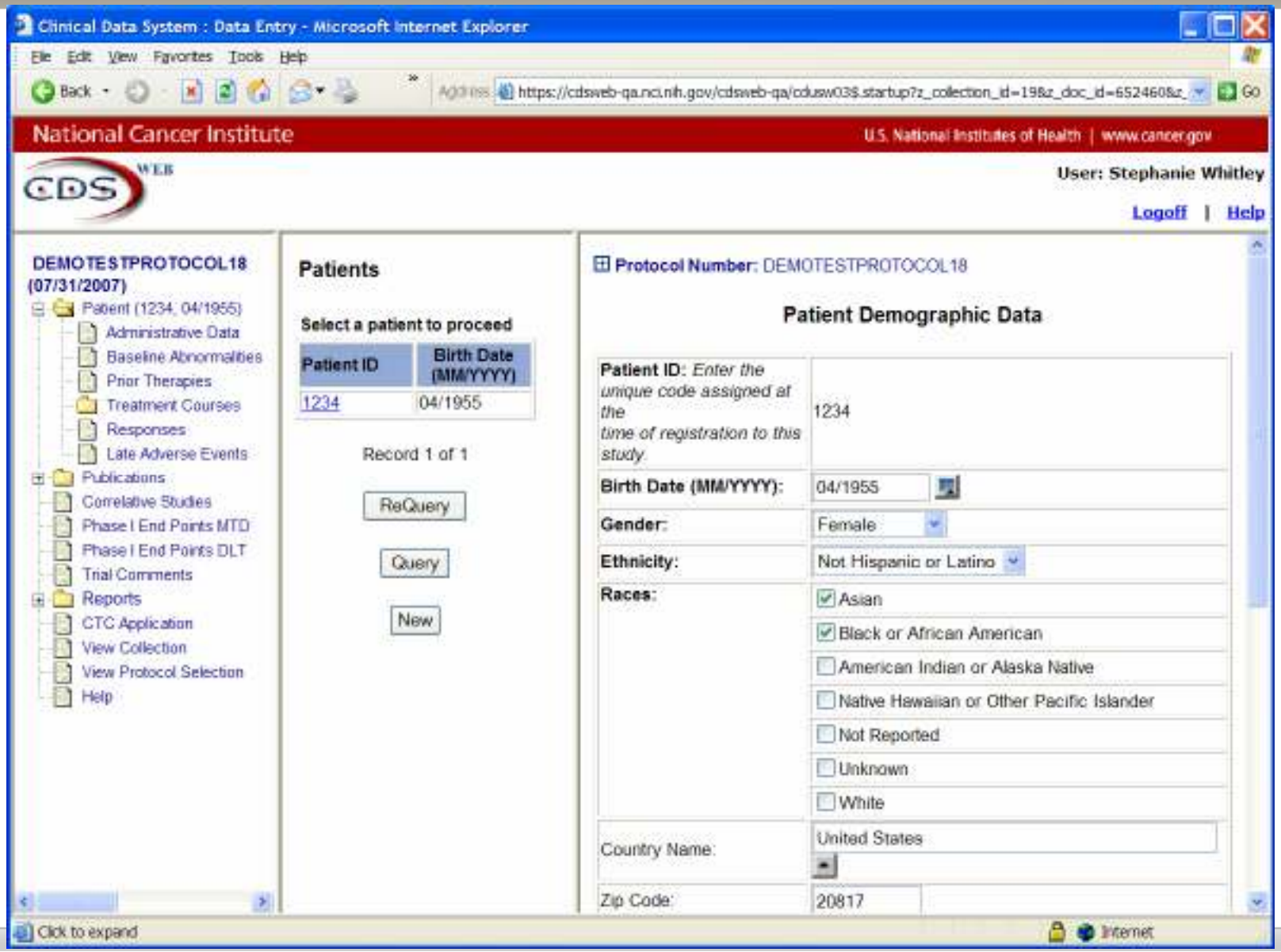
Clinical Data System (CDS) Web Interface



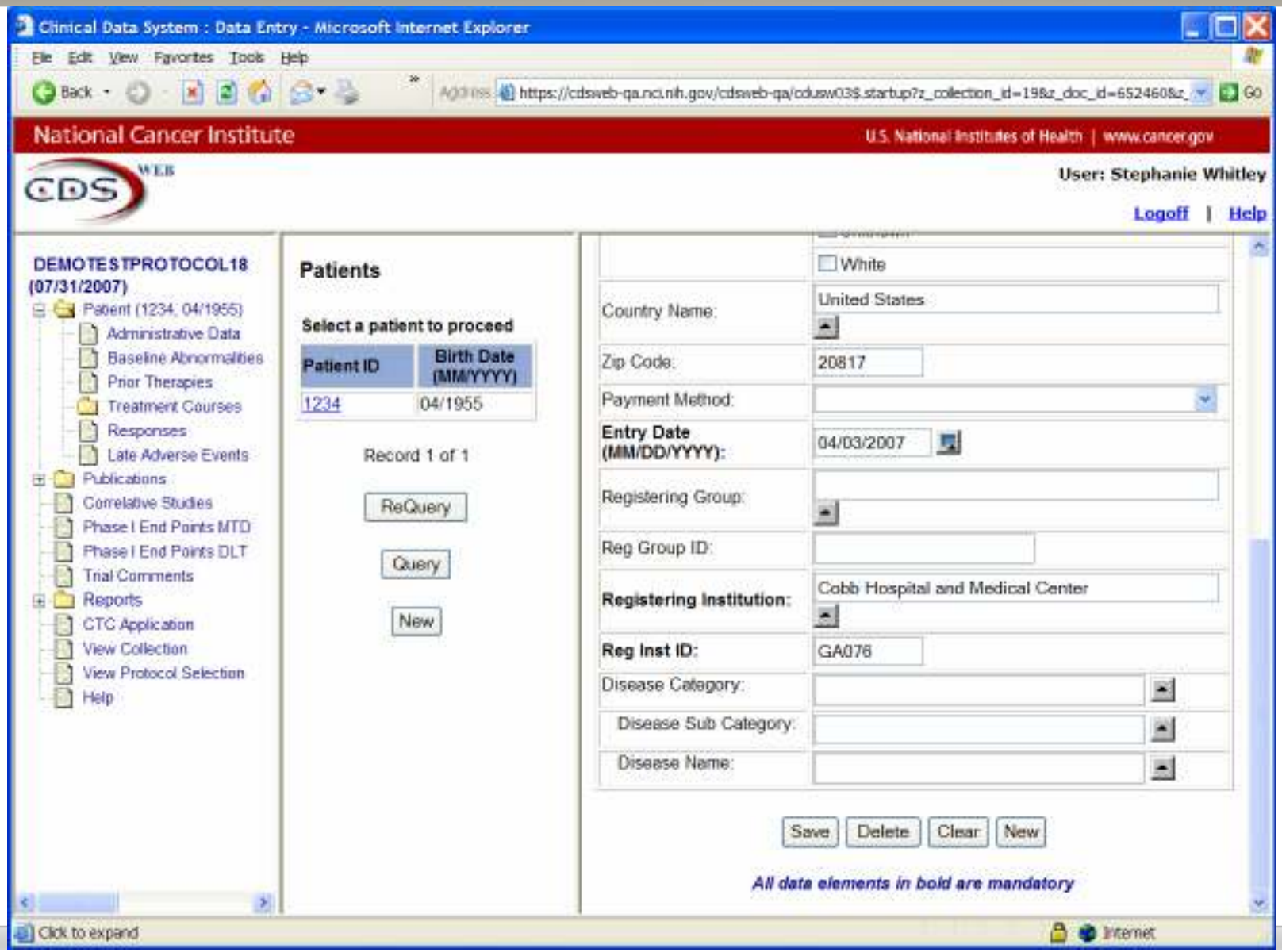
CDS Submitter Information



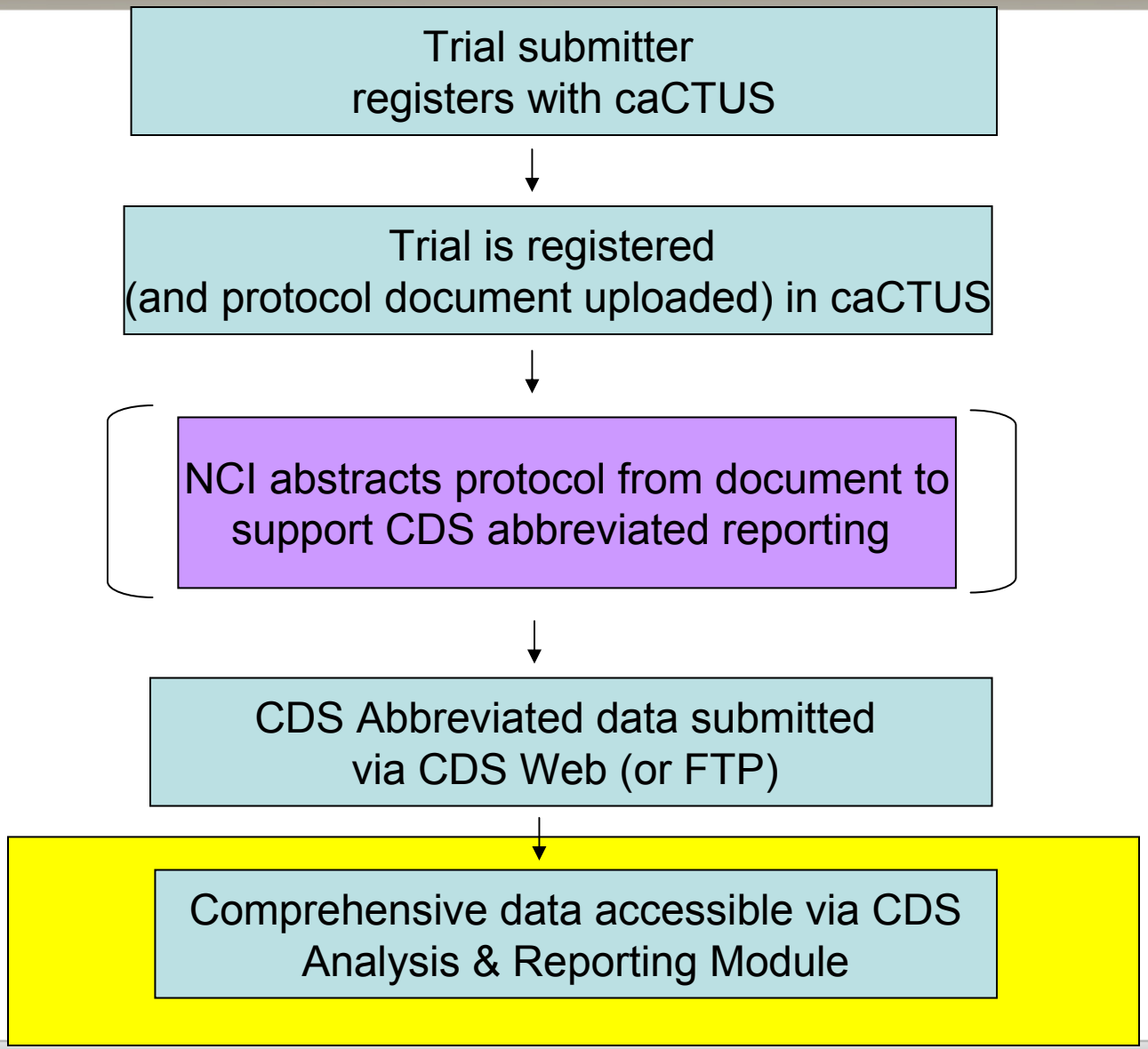
CDS Patient Demographics



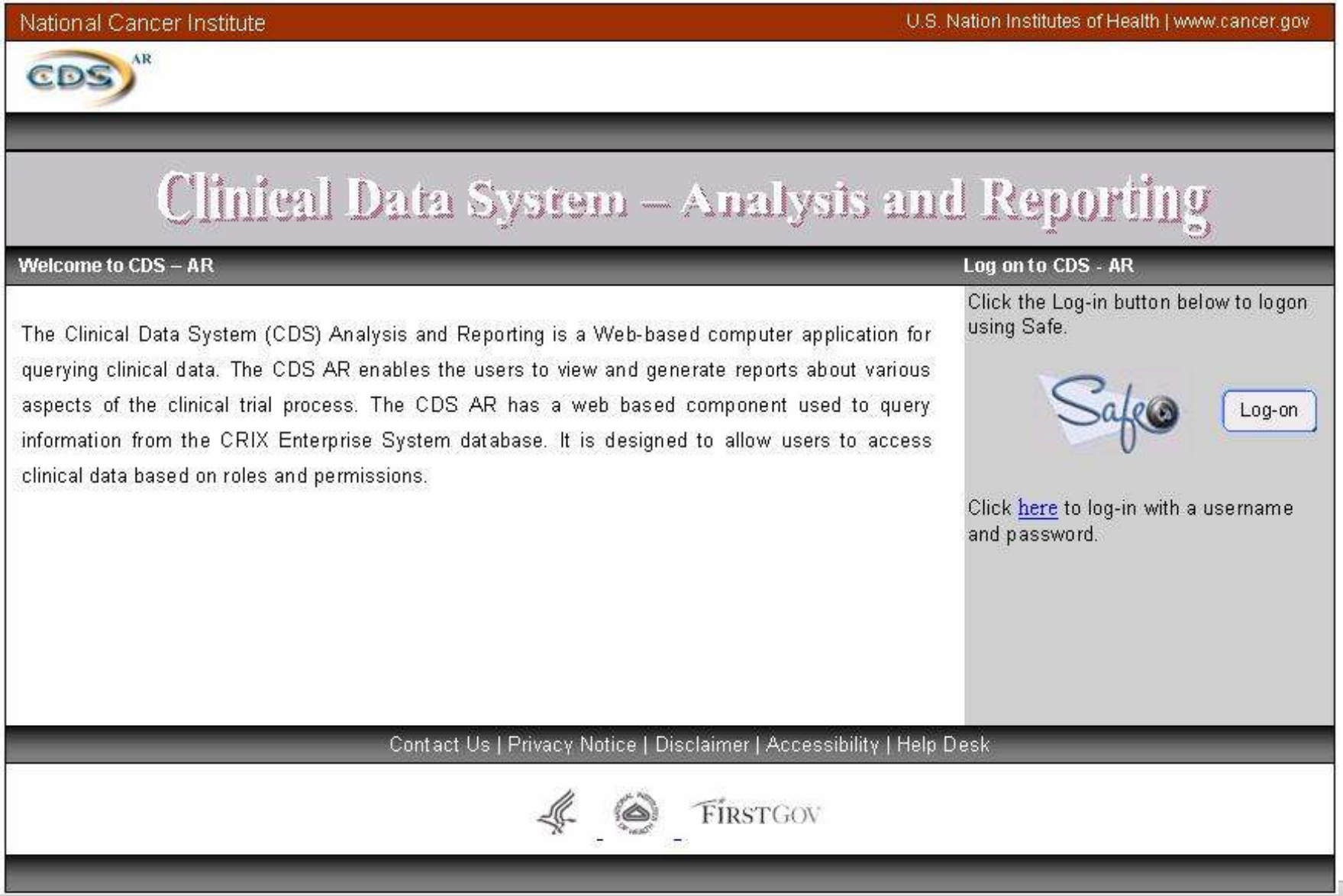
CDS Demographics/Accrual



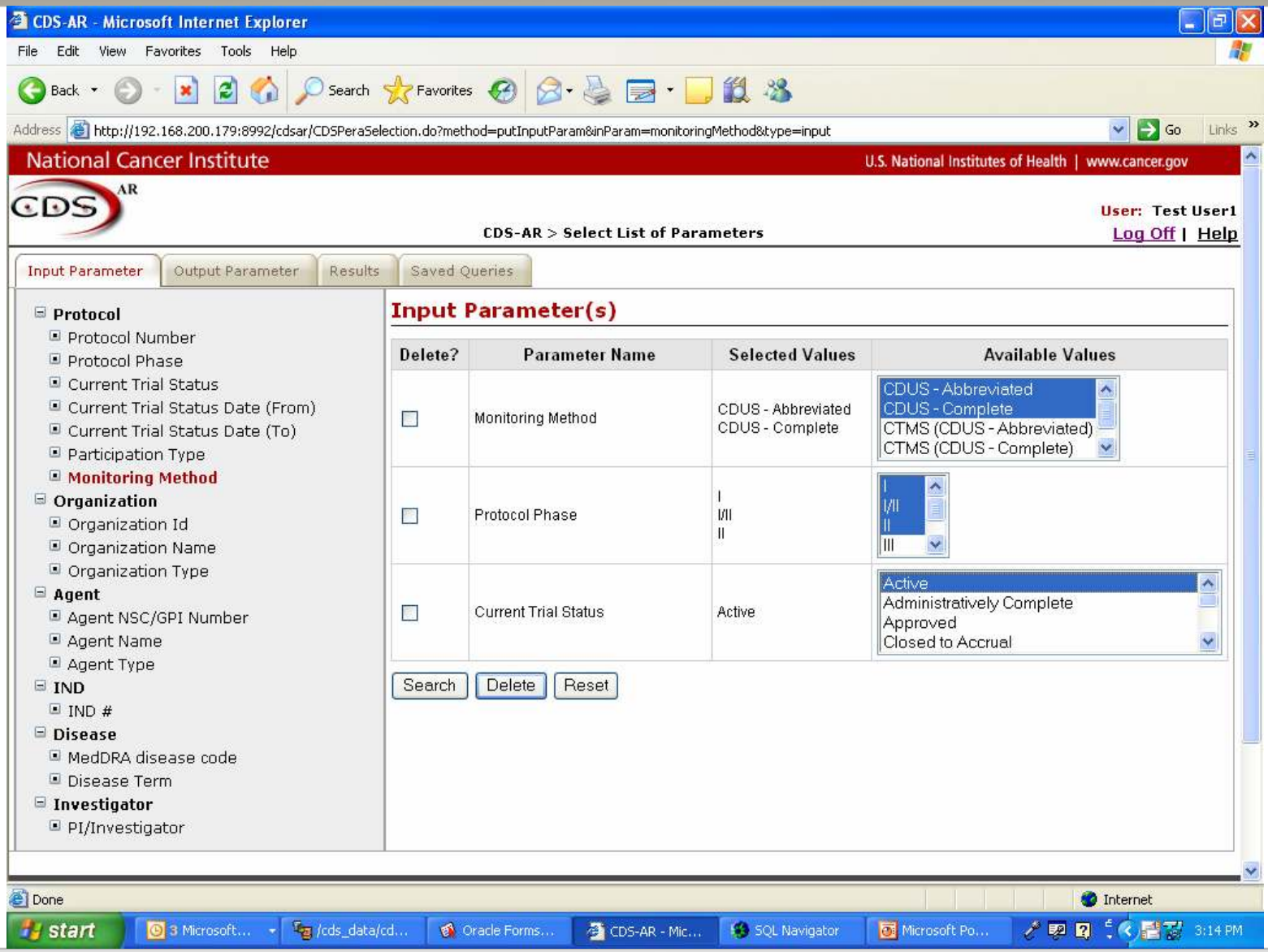
Proposed First Iteration of CTDB



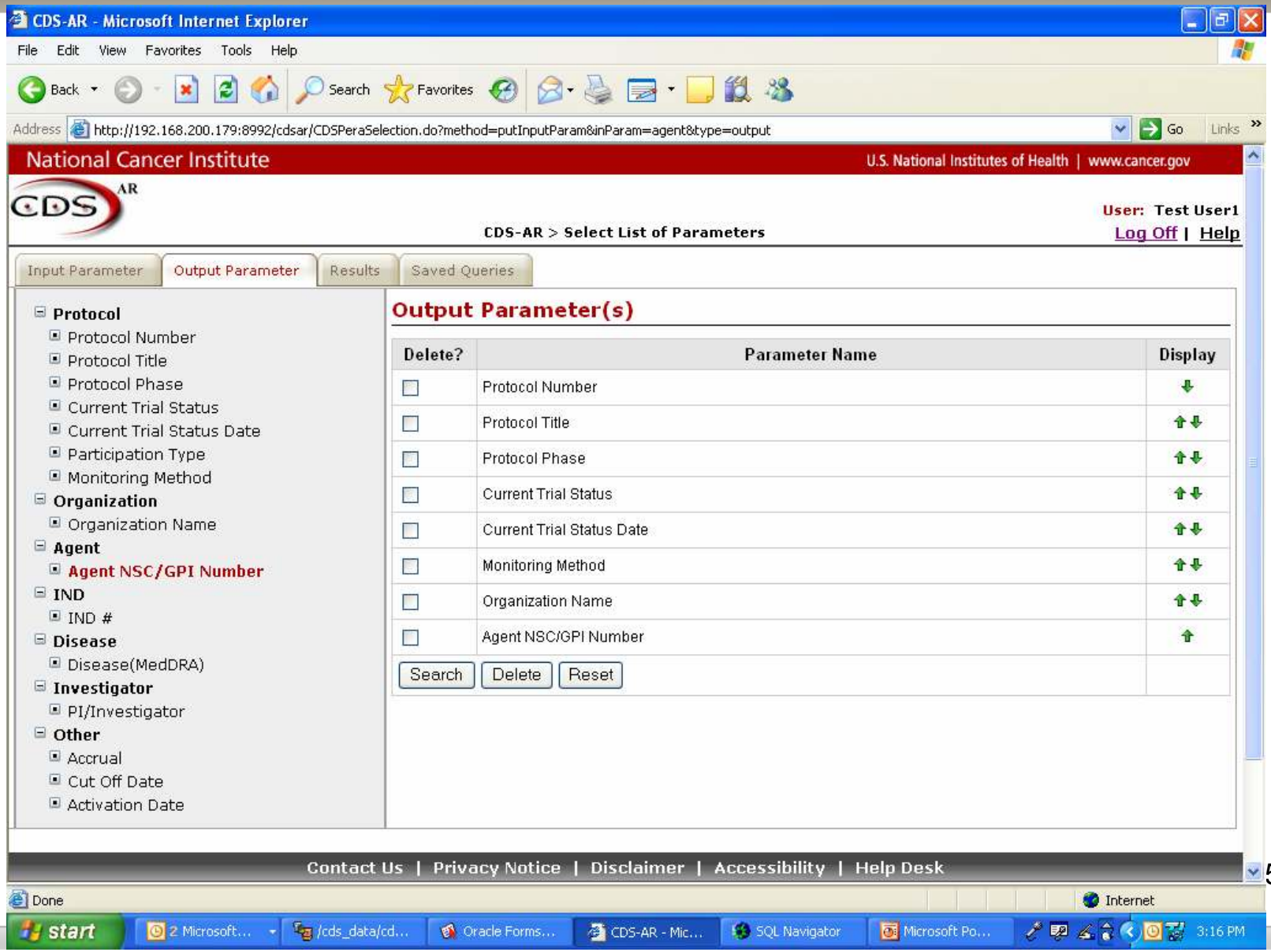
CDS Analysis & Reporting ("Sharing" CTEP CDUS Reports)



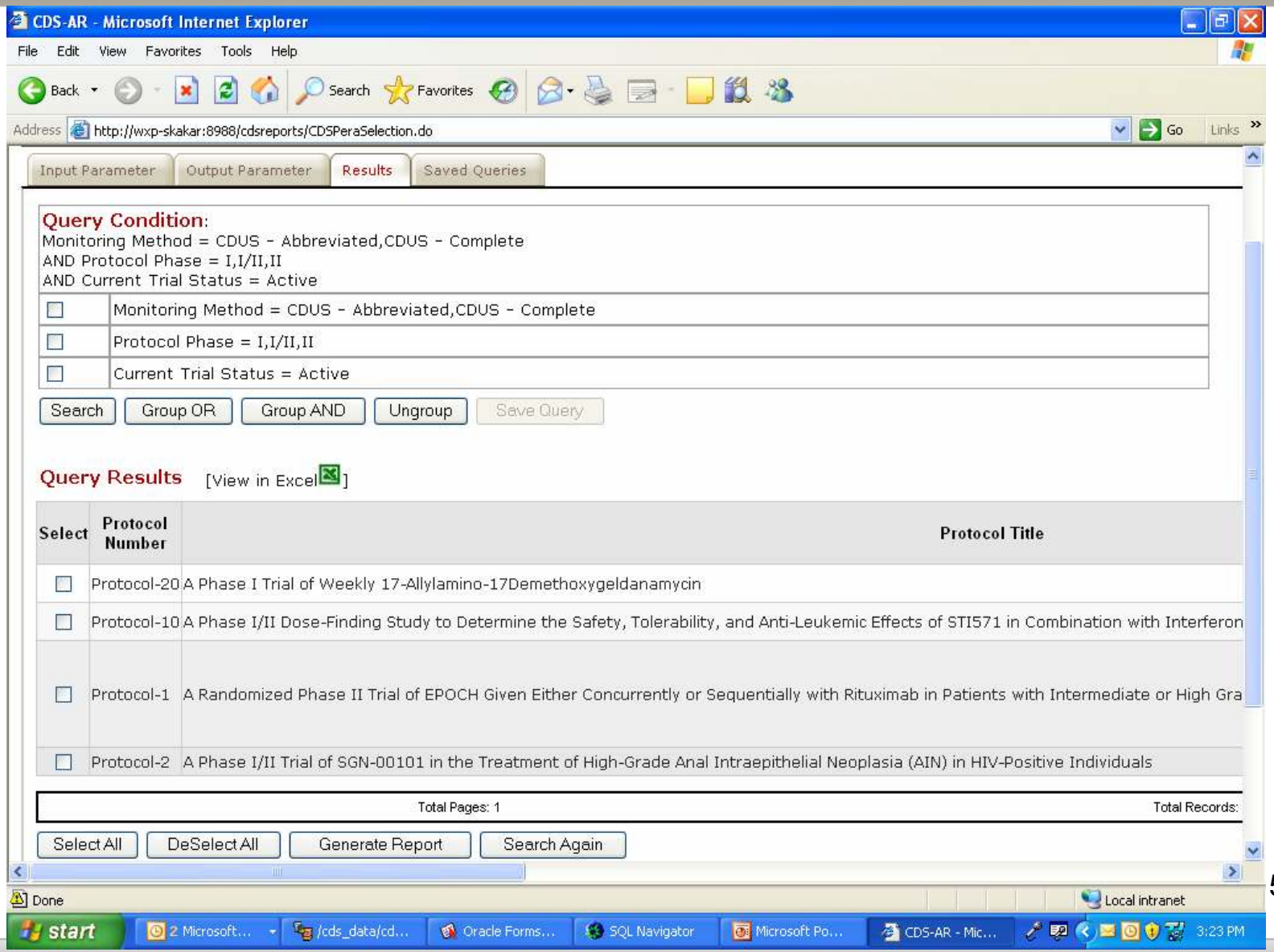
Input Parameters for Protocol Query



Output Parameters for Protocol Query



Protocol Query Results (and Saved Queries)



Available Reports for Selected Protocols

Next Steps

- **Develop new NCI Policy to ensure all trials are reported**
  - CCCT led activity
- **Assemble NCI Policy Implementation Team to address:**
  - “Legacy” data migration
  - Protocol abstraction
- **Ensure generation of Summary 4 and PDQ and ClinicalTrials.gov submissions**
  - Summary 3 will require non-accrual data
- **Develop timeline to coordinate activities**

Agenda

- Meeting Objectives
- Introductions
- SIG Meeting Schedule
- Overview of CTMS Workspace
- Overview of Reporting / Sharing SIG
- Clinical Trials Database (CTDB)
- **Comment, Feedback, Questions**
- **Review of Action Items**

Thank you! Q & A